EXHIBIT 42

McKesson Operations Manual
for Pharma Distribution

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Controlled Substance Monitoring Program

General Description	Contributing Authors	Overview of Detailed Steps	Detailed Steps	Attachments
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General Description

Task: This procedure outlines requirements and activities to proactively monitor customer's orders and purchases of DEA controlled substances and actions to take based upon analysis of customer orders and purchases.

Purpose: The purpose of this process is to:

- Proactively review the customer's orders and purchases for all controlled substances in order to detect and prevent diversion.
- Set and maintain customer's thresholds for all controlled substances
- Make informed decisions based upon established threshold information
- Build a documented business case to substantiate the volume of controlled substances purchased by McKesson customers.
- Report to the DEA those orders / purchases / customers designated as "suspicious".

The DEA expects McKesson to "*know their customer*". This means understanding the customer's business, *why* they purchase as well as how much they purchase. Factors such as type of business, internet activities, type and quantity of products purchased should be considered when evaluating a customer.

Reports

There are multiple reports developed to allow McKesson to monitor customer orders and purchases of controlled substances by the net number of dosage units sold based on the DEA's Controlled Substance Generic Base Code ID. McKesson will investigate customer activity when an order of a given generic base ingredient exceeds a predefined dosage unit threshold within a calendar month.

Additions or deletions of items will be managed through the Regulatory Department by submitting a problem request to Business Intelligence- Functional (BI-FUNC).

For the purpose of these reports, all sales to a DEA license number are being accumulated, therefore sales to multiple account numbers with the same DEA license number are consolidated. Sales are added together regardless of fill dc.

When to do: Daily
As needed

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Contributing Authors

The following are subject matter experts who contributed to this document:

Tracy Jonas

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Overview of Detailed Steps

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Detailed Steps

1. Thresholds

1.1 Initial Program Thresholds

Analysis was conducted on every McKesson customer. Thresholds with an additional margin were established based upon a review of customers' purchases over a twelve month period.
DEA has assigned each controlled substance to a "base code" or also referred to as the "Administration Controlled Substance Code Number".
The controlled substance thresholds were established using the DEA base code.

1.1.1 Regulatory Threshold Limits

The Regulatory Directors determined "Regulatory Limits" for every base code. The regulatory limits are conservative beginning dosage amounts that allow a pharmacy to order controlled substances until such time that individual thresholds can be set.

1.1.2 Family Threshold Limits

All McKesson customers were evaluated and classified into like business segments based upon type of business and monthly dollar RX sales. Additionally, Six Sigma analysis helped to identify appropriate threshold amounts for every controlled substance and for every family type. Out of that information, a matrix of family codes and threshold amounts were developed. (See attachments)

NOTE: If a customer has never purchased a particular "base code" before, Immediately upon their first purchase, the family threshold limit for that base code will be applied.

1.2 Establishing "New Customer" Thresholds

As McKesson accepts new customers, consideration needs to be given to establishing thresholds for controlled substances. Decisions will be made on a case by case basis using the guidelines listed below.

1.2.1 Retail National Account (RNA), MHS, Government Customers

Correspondence will be between McKesson sales and the customers corporate headquarters. Sales will obtain the necessary information so McKesson's regulatory department can establish appropriate thresholds.

How to do:

Upon contract signing of new account(s), customer will provide to McKesson national accounts a completed customer questionnaire (see on-boarding process in step 3 below). In addition, customer will provide at least 3 months sales history (at store level) consisting of:

- NDC number
- Item description with unit of measure
- Purchase quantity (either saleable units or dispensing units)
- Months purchased

Result:

Once the above data has been obtained it should be disseminated as follows:

- Original completed questionnaire to be retained at the DC in the CSMP file as described in the document retention section 5 below.
- Copy of completed questionnaire to be sent to appropriate Director of Regulatory Affairs
- Sales history data to be sent to Supply Chain Services/Inventory Analytics in Carrollton

A. Regulatory Affairs
   1. Directors will review completed questionnaire and based upon the information contained, assign the appropriate "family code" to each customer account.
   2. Directors will either;
      a. forward Excel spreadsheet listing family code assignment and account information to masterdata2@mckesson.com as approval to load family code to master data. To be loaded within 24 hours of receipt days of initial receipt
      b. input family and account data into RxPad as approval. To be loaded within 24 hours of input.
   3. Once receipt of loading has been received, DRA will notify Sales Rep, SA and DC

B. Carrollton Analysis
   1. Purchase history data will be analyzed and imported into a "CSMP Purchase History Spreadsheet" and forwarded to DRA.
   2. DRA analyzes the data, determines threshold amounts and uploads data to CSMP/SAP site
   3. DRA's will receive immediate indication of successful upload
   4. DRA will notify national accounts upon completion of threshold upload.

Special warnings:

NOTE: If no purchase history is provided, the customers' thresholds will remain at the associated family designation.

If an error occurs:

If the RX Pad system is not available and/or the Director of Regulatory Affairs does not have access, the approval process for DEA Family uploading can be maintained via an email attachment whereby the Director gives approval.

1.2.1.1 Existing Customer / New Location

As the customer relationship is pre-existing, national accounts and regulatory have previously reviewed the customers' controlled substance requirements. Correspondence will be between McKesson National Accounts and the customer's corporate headquarters. National Accounts will obtain the necessary information so McKesson's regulatory department can establish appropriate thresholds.

How to do:

A. National accounts will notify the appropriate regulatory directors via email of an anticipated new location opening.
B. Email to contain, Store name, Location, chain ID, DEA # and date of anticipated store opening
C. DRA will ascertain the default family code based upon previous analysis of customers existing locations and reply via email with family code and their approval to load into master data within 2 business days.

D. As the new location has no previous sales history, the default family and associated thresholds will be utilized until such time the locations purchases warrant threshold review.
E. DRA will respond to national accounts upon completion of threshold assignment.

If an error occurs:
If the RX Pad system is not available and/or the Director of Regulatory Affairs does not have access, the approval process for DEA Family uploading can be maintained via an email attachment whereby the Director gives approval.

1.2.2 All Other Account Types (independent, mail order, etc)

Correspondence will be between McKesson sales and the customers corporate headquarters/home office and/or owner. Sales will obtain the necessary information so McKesson's regulatory department can establish appropriate thresholds.

How to do:
Upon contract signing of new account(s), customer will provide to McKesson sales representative a completed customer questionnaire (see on-boarding process in step 3 below). In addition, customer will provide at least 3 months sales history consisting of:

- NDC number
- Item description with unit of measure
- Purchase quantity (either saleable units or dispensing units)
- Months purchased

Result:
Once the above data has been obtained it should be disseminated as follows:

- Original completed questionnaire to be retained at the DC in the CSMP file as described in the document retention section 5 below.
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      a. forward Excel spreadsheet listing family code assignment and account information to masterdata2@mckesson.com as approval to load family code to master data. To be loaded within 24 hours of receipt days of initial receipt
      b. input family and account data into RxPad as approval. To be loaded within 24 hours of input.
   3. Once receipt of loading has been received, DRA will notify Sales Rep, SA and DC

B. Carrollton Analysis
   1. Purchase history data will be analyzed and imported into a "CSMP Purchase History Spreadsheet" and forwarded to DRA.
   2. DRA analyzes the data, determines threshold amounts and uploads data to CSMP/SAP site
   3. DRA's will receive immediate indication of successful upload
   4. DRA will notify national accounts upon completion of threshold upload.

If an error occurs:
If the RX Pad system is not available and/or the Director of Regulatory Affairs does not have access, the approval process for DEA Family uploading can be maintained via an email attachment whereby the Director gives approval.

1.3 Threshold Change Requests

Existing customers may request a re-evaluation or increase to their existing controlled substances threshold due to business requirements and/or and emergency situation. All requests for a threshold change must be documented on the "Threshold Change Request" form as directed below.

NOTE: All requests for normal threshold changes need to be completed by a McKesson account manager and /or McKesson DC management. Emergency threshold requests may be initiated through the DC management.

1.3.1 Ordinary Threshold Change Request

The decision process time frame will vary depending on the nature of the request, availability of documentation and previous due diligence

How to do:

STOP! All Retail National Account customers' requests for a threshold increase must be submitted to, reviewed by and approved by RNA sales and the customer's associated home office or regulatory department. Threshold change requests can be forwarded to your DRA for proper handling.

A. DC management and/or sales rep completes the threshold change request form. **It is important that the form is filled completely and legibly.**
   1. Complete the date
   2. Customer Name and complete address
   3. DEA # (required)
   4. Customer account #
   5. Complete in detailed item information including; Econo #, selling description and NDC#
   6. Enter the amount increase of the controlled substance either as a % increase or amount of selling unit.
   7. Complete in detail the reason(s) for threshold change. It is important to attach any supporting documentation (i.e. business agreement, sales analysis, etc).

B. McKesson Use Only
   1. (if form was completed by McKesson Sales Rep) McKesson sales rep will contact the DCM of the servicing distribution center to complete the "McKesson Use Only" area. questions 1-4.
   2. DCM can deny threshold change request at any time by completing "denied by" area on form and notifying sales rep and their DRA.
   3. If DCM approves threshold change request it will be forwarded to DRA for final review and rejection/approval.
   4. If DRA approves, threshold change will be effective as of the date of approval and DRA will notify sales rep / DCM via email.
   5. If DRA denies, they will contact the DCM /sales rep and inform them of the outcome via email.

1.3.2 Emergency Threshold Change Request.

The decision process time for an emergency request shall be 2 hours from the point of customer contact

How to do:

A. The decision of whether a request is truly an emergency lies with the DC management.
   1. Once the DC management has determined that a request is an emergency, the DC management will collect all the pertinent information regarding the request on the Threshold Change Request form.
   2. If the DC management approves the request, they will contact their DRA (24/7) via the contact call chain described here: (phone numbers previously communicated)
      a. Contact your region's DRA (office/cell/home). If not available
      b. Contact Gary Hilliard (office/cell/home). If not available
      c. Contact any other DRA (office/cell/home)
   3. If the DRA concurs with the DC management's assessment, they will update the customers' thresholds immediately.
   4. DC management will notify the customer immediately upon approval of the threshold change.
   5. If DC management and/or DRA rejects request, customer is to be notified immediately by DC management of denial.
   6. All results (denial or acceptance) are to be documented on threshold change form and retained by DC management(with copy to DRA) in CSMP file.

1.3.3 DRA Required Standard Text

This step is a requirement for Directors of Regulatory Affairs only

When making any change to a customers threshold (temporary and/or permanent) you will need to enter text in the text field before a threshold will be accepted.

Special warnings:
NOTE: Only the standard text is acceptable.

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2. Threshold Review

Regulatory department will review/assess customer thresholds during the month. Additionally, customers that approach a predetermined % of threshold maximum or exceed maximums will receive messaging as shown below.

- Threshold Warning: Invoice & Delivery Doc only
  - **Approaching Monthly Regulatory Purchase Limit**
- Omit Code V: Threshold Limit
  - Short Message on some Front End Systems: **Monthly Max Exceeded**
  - Long Invoice Message: **Monthly Regulatory Maximum Purchases Exceeded**

NOTE: See example of invoice in attachments!

2.1 Threshold Warning

When a customer that has reached the threshold warning has been detected, The DRA will notify DC management and sales. Sales and/or DC management may contact the customer to discuss threshold levels at their discretion. If a threshold change is requested, follow the change request process in step 1.3 above. Any communication with customers must be documented (using general communication form in attachments) and retained in the CSMP file.

2.2 Threshold Excursion

Once a customer has reached their monthly maximum threshold amount, all subsequent orders for that item will be blocked. This triggers the level review process as detailed in Level review steps below.

The only way an item can be "unblocked" is if
· Threshold is temporarily changed
· Threshold is permanently changed
· Customer returns product and they fall below threshold
· Sales history is "refreshed" at the beginning of a new month, meaning sales are set back to zero and customer is once again allowed purchase up to threshold amounts.

2.2.1 Level 1 Review - RNA Customer

The RNA support team will be responsible for initiating/compiling the level 1 review for RNA customers.

How to do:
Once the RNA support team has been informed of the threshold incursion, they will

- notify and request information from one of the following: the customers regulatory department, corporate office, regional management team or McKesson liaison regarding the item(s) in question.
- solicit feedback from the RNA customer and document information on the General level 1 form in the attachments section. RNA support team will include all pertinent information as directed in the form; as well as the name, title, phone of person contacted/providing information.
- forward copies of level 1 documentation to appropriate Director of Regulatory Affairs
- initiate a threshold change requests if needed (see section 1.3 above).

Result:
Once received, the DRA will forward the level 1 documentation to appropriate DC.

Special warnings:
If during this level 1 process either the RNA support team or the DRA determines it warranted, a level 2 review can be initiated as directed in step 2.2.3 below.

2.2.2 Level I Review - All Remaining Customers

A level I review is required for every threshold incursion.

How to do:
DC management will contact the customer upon attempted threshold incursion. At a minimum management will inform the customer that a controlled substance was omitted because a threshold maximum was met, ascertain the reason for the threshold incursion, inquire as to any new business that the customer may be servicing and document the conversation. Based upon management's evaluation of the conversation the level 1 may be complete. If however management feels further evaluation is necessary, they may evaluate the customer's purchases relative to the past three month's purchases. The evaluation should include but not necessarily be limited to the following criteria:

- Review Customer Purchasing Profile if one has been completed; are sales consistent with their profile?
- Perform a web search on the customer to review possible business practices
- Contact the appropriate Sales representative to determine reasoning behind the sales.
- Contact the customer to inquire on sales volume, expected volume and nature of business.
- Previous sales were validated and approved.
- Sales have not increased more than 25% from any previous month.
- Sales are not increasing steadily.
- Sales are consistent with the customer type.
- Sales are consistent with any previous Sales or Customer communication.

NOTE: DC management will document all conversations with customer utilizing the general communication form in the attachments section, retain all email pertaining to customer review and all other data utilized in the level I review. Documentation will be retained in the customers CSMP file as evidence of due diligence.

Result:
If the evaluation indicates that the customer's purchases are reasonable and that no further investigation is required, DC management will decide to:

- Continue to block item until the beginning of new month and sales history is refreshed. This will need to be communicated to the customer by either DC management or sales.
- Request a temporary/permanent threshold change by following step 1.3 above.

Special warnings:
If the evaluation is not conclusive:

- Escalate to the Level II Review

2.2.3 Level II Review

If the Level I Review as conducted by DC management / RNA support team is deemed inconclusive, a Level II Review is required.

How to do:

1. DC management will forward/communicate all Level I information to their DRA.
2. DRA and DC management will discuss review process and conduct customer interview(s) if appropriate. (Refer to "Due Diligence" in section 4 below)
3. DRA along with DC management will determine if sales are appropriate and either;
   a. inform customer that sales of the item will be blocked until the beginning of the next month
   b. implement a temporary/permanent threshold change by following step 1.3 above.

NOTE: RNA support team shall be substituted for DC management as required in the above steps. All conversations with customer will be documented. All parties will retain all email pertaining to customer review and all other data utilized in the level II review. Documentation will be retained in the customers CSMP file at the regulatory DC as evidence of due diligence.

2.2.4 Level III Review

If after the Level I and Level II reviews have been conducted and the transaction (s) are deemed "suspicious", a Level III review is necessary.

How to do:

1. Upon escalation to Level III, **ALL** controls will be blocked.
2. The matter will be escalated to the SVP of Distribution Operations, Regional SVP, RNA VP (as needed) VPDO, VPGM and Regulatory Affairs.
3. The customer / transaction (s) are reported to DEA Headquarters as "suspicious". The local DEA office should be contacted to determine if the account is in good standing with the agency; this will be done by DC Management or Regulatory Affairs. Findings must be shared between DC Management and Regulatory Affairs.
4. Regulatory Affairs will schedule and conduct meetings with the Law Department and Senior Management to present the findings of the review process and discuss next steps.
5. With the Law Department's guidance, Regulatory Affairs or Counsel will contact the DEA Headquarters to discuss our findings.
6. The final review of customer purchases and decisions regarding their purchases will be determined by the Law Department and Senior Vice President.
7. Regulatory Affairs will notify the DEA Headquarters and Local Office of McKesson's findings and any decisions regarding continued business with the customer.
8. If there are outcomes to the review that impact the customer relationship with McKesson, Sales or Distribution Management will notify the customer.

2.3 Threshold Removal

If at any time there is need to remove the customer's ability to purchase controlled substances, either completely or by base code, the DRA can make adjustments as detailed below.

How to do:

1. Block All Control Substance Purchases
   a. Sales Admin can remove the DEA number from customer master data or
   b. DRA can remove family code via threshold maintenance in SAP
2. Block Specific Base Codes
   a. The DRA can enter "0" into threshold amount for specific base code (s)

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3. New Customer On Boarding Process

It is extremely important as part of McKesson's ongoing commitment to Controlled Substance Monitoring and understanding our customers business practices that Sales and Operations work collaboratively to inform, investigate and authorize all new customers controlled substance purchases.

Special warnings:
Failure to complete all required forms or information will prevent or limit sales of controlled substances to customer.

3.1 Introducing new McKesson customers to Controlled Substance Monitoring (CSM)

How to do:
During the customer on-boarding process, the McKesson sales representative will introduce the CSMP. The sales rep will utilize the CSMP communication letter, CSMP Overview and CSMP FAQ (see attached) to inform customer of McKesson's responsibility and customers requirements.

Special warnings:
NOTE: At no time is there a guarantee, implied or otherwise, that any customer will be able to purchase controlled substances based upon information received during this process.

3.2 Customers Questionnaire

How to do:
Upon explanation/ presentation of McKesson's CSMP process, the sales rep will present, explain and request signatures for the "Customers Declaration" (see attachments)

Special warnings:
NOTE: All customer questionnaires must be completed **legibly and completely.**

3.2.1 RNA, MHS, Government, Customer Questionnaire

Because RNA, MHS and government customer's typically have their own regulatory departments and oversight, the abbreviated customer questionnaire form can be utilized. It may be completed by the customers home office or controlling branch on behalf of all of their operating units and/or stores.

3.2.1.1 Header Portion

If customer questionnaire is being completed on behalf of multiple locations, attach/submit electronically the detailed information (as noted below) for each location.

How to do:
Indicate whether new account is a new customer or existing customer.

New customer = New account not currently serviced by McKesson
Existing customer = Account currently serviced by McKesson, opening additional location (s) and/or secondary/warehouse account that is becoming primary with McKesson.

Indicate the number of locations/stores being activated and estimated "go-live" date.

3.2.1.2 I. General Information & Licensing

How to do:
i. Pharmacy Name (enter pharmacy / customer name as it appears on DEA registration)

ii. Pharmacy Address (enter information as it appears on DEA registration)
iii. Pharmacy License (include all states in which licensed) Photo copy of all phcy licenses
iv. DEA registration number (list number on form and photo copy)

3.2.1.3 II Ownership/Business History

Complete sections as indicated. Utilize the explanation box to explain and/or include any other relevant information

How to do:
a. Ownership type (indicate by check mark the business type)
b. Number of years in operation
c. History

3.2.1.4 III Business Information

Complete sections as indicated. Utilize the explanation box to explain and/or include any other relevant information

How to do:

a. Business Type (circle the type of business this customer represents)
b. List wholesale distributors used in the last 24 months
c. How does pharmacy receive business. List estimated %.
d. Is the pharmacy affiliated with an internet website or has its own site? (list address)
e. Is the pharmacy "Verified Internet Pharmacy Practice Site" (VIPPS) certified?
f. Does pharmacy download / fill prescriptions from a website?
g. Pain management clinics (Indicate the % of the customers overall business which is attributed to pain management business. Detail any pain management clinics that customer may be doing business with. Include a listing of individual customer(s) and their associated pain clinic (s).)
h. Does pharmacy service nursing homes, long term care or hospice facilities?
i. Is pharmacy located in a medical center or clinic?
j. Is this a closed door pharmacy?
k. Does pharmacy regularly fill prescriptions written by out of state providers?

3.2.1.5 IV Purchasing Information

In order to understand the new customers current controlled substance purchase requirements it is necessary to obtain past controlled substance purchasing information. File should be provided electronically.

How to do:

At least 3 months sales history is required which will include:

a. NDC
b. Item Description
c. Purchase Quantity
d. Unit of Measure
e. Purchase Date

If sales history is not available, 3 months of dispensing information should be obtained.

Inquire as to if the pharmacy has established policies and procedures to verify controlled substance prescriptions and if so, how.

3.2.1.6 Customer Signature and Attestation

Upon completion of the customer questionnaire, the owner, representative and/or designee will sign/date and attest to the documents accuracy and completion.

3.2.2 All Remaining Accounts Questionnaire

A completed customer questionnaire is mandatory for every new McKesson customer prior to them receiving controlled substances. The regulatory department must approve new customer(s) based upon questionnaire information/supporting documentation prior to threshold setting.
The customer is not allowed to complete the questionnaire themselves, the questionnaire is meant to document interactive communications between McKesson and the customer. The questionnaire will be completed by the McKesson sales representative.

Special warnings:

Customer will not be allowed control substance purchases without regulatory approval based upon completion of customer questionnaire and supporting documentation.

3.2.2.1 Header Portion

If customer questionnaire is being completed on behalf of multiple locations, attach/submit electronically the detailed information (as noted below) for each location.

How to do:

Indicate whether new account is a new customer or existing customer.

New customer = New account not currently serviced by McKesson
Existing customer = Account currently serviced by McKesson, opening additional location (s) and/or secondary/warehouse account that is becoming primary with McKesson.

Indicate the number of locations/stores being activated and estimated "go-live" date.

3.2.2.2 I General Information & Licensing

How to do:

a. Pharmacy Name (enter pharmacy / customer name as it appears on DEA registration)
b. Pharmacy Address (enter information as it appears on DEA registration)
c. Phone/Fax
d. Pharmacy Email address (if applicable)
e. Pharmacy License (include all states in which licensed) Photo copy of all phcy licenses
f. DEA registration number (list number on form and photo copy)
g. Pharmacist License (list all pharmacists' licenses, the state and license number. Indicate the Pharmacist in Charge (PIC).)

3.2.2.3 II Ownership/Business History

Complete sections as indicated. Utilize the explanation box to explain and/or include any other relevant information

How to do:

a. Owner information (complete only if owner differs from PIC)
b. Ownership type (indicate by check mark the business type)
c. Number of years in operation
d. Owner operates/affiliated with additional pharmacies? (if so, list)
e. History

3.2.2.4 III Business Information

Complete sections as indicated. Utilize the explanation box to explain and/or include any other relevant information

How to do:

a. Business Type (circle the type of business this customer represents)
b. List wholesale distributors used in the last 24 months
c. How does pharmacy receive business. List estimated %.
d. Is the pharmacy affiliated with an internet website or has its own site? (list address)
e. Is the pharmacy "Verified Internet Pharmacy Practice Site" (VIPPS) certified?
f. Does pharmacy download / fill prescriptions from a website?
g. Pain management clinics (Indicate the % of the customers overall business which is attributed to pain management business. Detail any pain management clinics that customer may be doing business with. Include a listing of individual customer(s) and their associated pain clinic (s).)
h. Does pharmacy service nursing homes, long term care or hospice facilities?
i. Is pharmacy located in a medical center or clinic?
j. Is this a closed door pharmacy?
k. Does pharmacy regularly fill prescriptions written by out of state providers?

3.2.2.5 IV Purchasing Information

In order to understand the new customers current controlled substance purchase

requirements it is necessary to obtain past purchasing information.

How to do:

a. Total estimated monthly RX purchases including controlled substances.
b. Purchase breakdown (approximate)
c. Prescriptions filled per day/month
d. Method of payment to pharmacy (estimate)

3.2.2.6 V Controlled Substances Purchases

McKesson requires specific usage information for lifestyle type substances (Hydrocodone, Oxycodone, Alprazolam, Phentermine, Methadone) in order to assess the customers' current requirements.

How to do:

a. Estimate dose units dispensed per month for each of the following controlled substances, hydrocodone, oxycodone, alprazolam, phentermine and methadone. This information should contain the total for all brand and generic for the base ingredient including combination products
   - 1 tab, cap = 1 dose
   - 1 ounce = 1 dose
   - 1 ampul/vial/injection = 1 dose
b. If any of the above is greater than 5000 dose units, please provide information to support purchase levels. (Supporting information may include dispensing trend, referrals from pain clinics, etc)
c. Has the pharmacy established policies and procedures to verify controlled substances prescriptions? If so how?

3.2.2.7 VI Physical Inspection

An important part of the on boarding process and fulfillment of our obligation to "know our customer" is the site visit/observation process. First impressions are important and should be noted, however utilizing the questionnaire is a more formal way to memorialize the observation information.

How to do:

a. General description of pharmacy and surrounding area in which the business is located, include the condition of the pharmacy.
b. General description of the pharmacy customers.

The information listed here will assist in the site visit/observation.

Observations should include items such as the following:

- Customer Traffic - does the customer volume seem in line with their business type?
- Signage - does the customer advertise themselves to the public in a manner consistent with their business type?
- Location - is the customer's business in a site that appears consistent with their business type and volume? For example, consider the area's population and surrounding businesses.
- Store Size - does the customer's square footage appear to be appropriate for their business type and volume?

c. Does the pharmacy have adequate security?

Photograph pharmacy outside and inside, including front entrance, pharmacy interior and pharmacy counter.

3.2.2.8 Customer Signature and Attestation

Upon completion of the customer questionnaire, the owner and/or PIC will sign/date and attest to the documents accuracy and completion.

3.3 Customer Interview

How to do:

Instructions for performing the interview

1. Notify the appropriate Sales team member that an interview must be conducted with the customer.
2. Sales or Operations should contact the customer and request a meeting at a mutually agreed upon date and time. NOTE: All meetings should be conducted on the dispensing pharmacy premises in order to view the pharmacy operations.
    - Schedule the meeting for as soon as is possible for all parties; the DEA expects McKesson's responses to suspicious activities to be prompt and timely.
    - Ensure that the customer understands that McKesson is performing due diligence activities for the benefit of both McKesson and the customer.
3. Print and review the customer questionnaire prior to visiting the customer.
4. Conduct the interview.
5. Have the customer sign the questionnaire.
6. Thank the customer and exit the interview
7. Complete and sign the customer questionnaire based upon responses provided by the customer.

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4. Due Diligence

McKesson's responsibility is to "Know Our Customer". If at any time McKesson (this includes sales, operations, regulatory) suspects any wrong doing, inappropriate activity and/or questionable practices, McKesson has the responsibility to react. This requirement is regardless of customer type, size, tenure, revenue, purchase quantities or threshold amounts.

Regulatory and/or DC management may request a customer site visit, observation and/or signed questionnaire at any time. Regulatory may also suspend shipments of controlled substances at any time.

How to do:

Due diligence may include one or all of the following activities:

- Customer Declaration
- Site visit / observation
- Follow up interview
- Inquiries with local DEA, Board of Pharmacy
- Web search
- Requesting extensive background search via corporate security
- Photographs

1. Customer Communications
    - All communications regarding controlled substances are subject to subpoena and discovery.
    - Include in the subject line of emails, customer name and/or acct#
    - Write information as if it were being viewed by the DEA
    - Be complete and detailed...remember utilize the 5 W's
        - Who, what, when, where and why
    - Refrain from using the word "suspicious" in communications.
        - Once McKesson deems an order and/or customer suspicious, McKesson is required to act. This means all controlled substances sales to that customer must cease and the DEA must be notified.
    - Document ALL conversations where controlled substances are concerned or discussed. (use the standardized form in the attachments section)
    - Phone, intrapersonal conversations with customers should be documented and retained at the DC.

2. Legal Communications
    - Communications copied to McKesson's legal department must contain the following text:
    - **Privileged and Confidential**
    - This may be included in the subject line and/or the body of the text.
    - Doing so protects information as attorney client privilege.

Special warnings:

Any activity taken with regards to CSMP should be properly documented and retained. Emails, contracts, government contact

forms, notes from phone conversations, photos etc may be collected as evidence and as such should be legible, detailed and accurate.

4.1 TBD - reserved for future use

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5. Document Retention

It is imperative that documentation regarding CSMP is retained in an easily accessible/retrievable manner. This documentation can be requested by the DEA, State authority and McKesson Regulatory/Law department to support an investigation, audit or inquiry.

How to do:
All documentation related to CSMP will be maintained at the DC in a central location.
All DC's are required to maintain a 4 drawer file cabinet (minimum) that is for the sole and exclusive use of CSMP documentation. It will be marked as CSMP.

Emails and electronic copies are to be kept in the same manner in the CSMP file.

Government contact forms are to be disseminated as per distribution list on form.

GUIDING PRINCIPLE: Any CSMP document should be able to be retrieved within 30 minutes of request.

Special warnings:
Requests for information/documentation by DEA or other Authority must be accompanied by a written request and approved by McKesson Legal department prior to release of information.

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Attachments

Request to Increase Threshold
Click to Open or Save

General Level 1, Observation, Communication Documentation Form
Click to Open or Save

Family Matrix
Click to Open or Save

ISMC Questionnaire
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Invoice Example
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CSMP Customer Letter
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CSMP Overview

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CSMP FAQ

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Revision History

Revision #:
1.0
02/11/2008
Document Created

Revision #:
1.1
04/29/2008
first final draft

Revision #:
1.2
05/27/2008
Draft 2-added csmp file info, new threshold form, new documentation form

Revision #:
1.3
05/27/2008

Revision #:
1.4
06/16/2008
incorporated suggested verbiage changes as directed by outside counsel.

Revision #:
1.5
06/24/2008
Added ISMC Questionnaire

Revision #:
1.6
06/24/2008
Released to the Field

Revision #:
1.7
07/24/2008
added If an error occurs:

- If the RX Pad system is not available and/or the Director of Regulatory Affairs does not have access, the approval process for DEA Family uploading can be maintained via an email attachment whereby the Director gives approval.
to section 1.2

Revision #:
1.8
07/25/2008
added verbiage to level one review

Revision #:
1.9
08/18/2008
revision to level 1 / RNA process

Revision #:
1.10
08/18/2008
approval to post received

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No email? Send your comments to: **MOM Feedback**

McKESSON
Empowering Healthcare

McKesson Controlled Substances Monitoring Program

Program Guide for Pharmacies

Program overview

McKesson is enhancing our policies and practices for distributing controlled substances to our pharmacy customers. We have designed our Controlled Substances Monitoring Program (CSMP) to improve our ability to monitor orders of controlled substances.

With this program, we have put in place a sophisticated technology system that will allow for proactive, two-way communications between McKesson and your pharmacy.

Program details

All U.S. drug wholesalers have always been required by the DEA to monitor the ordering of controlled substances. Those regulations have not changed, but the extent to which wholesalers are now required to monitor and enforce the legitimate use of controlled substances has. While we trust and respect our customers' integrity and professionalism, we must cooperate with these mandates from the DEA.

Therefore, beginning this month, McKesson will implement the CSMP. Here's how the program works:

- McKesson will monitor purchases of all controlled substances by all customers.
- A critical component of this program is the establishment of controlled substance thresholds.
- Realizing that each customer's business is unique, McKesson has taken great care to set a threshold level specific to your business needs.
- Thresholds are determined by an analysis of each customer's controlled substances purchase history.
- Thresholds are monitored monthly and adjusted if necessary.
- Customers will be alerted in advance of meeting or exceeding their thresholds.
- Customers can apply for threshold adjustments if their business is changing or they anticipate needing to place a larger order.

Attachment 7

Notification system

Your McKesson ordering system conducts real-time monitoring of controlled substance purchases according to DEA base code. McKesson's CSMP works with your regular ordering system processes to deliver communications in plenty of time for your pharmacy to take corrective action, helping head off any potential disruptions in supply.

Advance warning alerts

If your pharmacy reaches a threshold for a given product, you will receive an alert in Supply Management Online or EconoLink, and a message on your invoice or delivery document, alerting you that you are approaching your regulatory purchase limit, so you can monitor your purchases for the rest of the month.

Threshold exceeded

If for some reason your pharmacy exceeds its threshold for a given product, you will see a "V" omit code in your ordering system, as well as printed on your invoice. The omit code signals that the product will be omitted from your order because you exceeded your monthly threshold.

Communicating anticipated order increases

We recognize your business is constantly changing, so your future controlled substance ordering needs may vary from your order history. McKesson has developed a Threshold Change Request process, allowing you to communicate your needs in advance so we can accommodate them in advance of any delays or disruptions in delivery.

McKesson values you and your business and is committed to working closely with you to ensure that your pharmacy continues to be successful. This program addresses the DEA's requirements to ensure controlled substances are used in the way they were intended, but it also ensures that you as a McKesson customer can continue with business as usual.

Your McKesson representative will be contacting you shortly to walk you through the new processes and answer any questions you might have.

Attachment 7

McKESSON
Empowering Healthcare

McKesson Controlled Substances Monitoring Program

FAQs for Pharmacies

1. Why is McKesson implementing this program?
McKesson and all wholesalers have always been required to monitor the distribution of controlled substances, and now the DEA is requiring all wholesalers to implement tighter controls. With our CSMP, we have developed a technology solution to automate the monitoring of controlled substances and proactively communicate with customers.

2. Is McKesson the only wholesaler required to implement this type of program?
No, all U.S. pharmaceutical wholesalers are being required to meet the DEA's requirements for tighter controls on controlled substances. The Controlled Substances Monitoring Program is McKesson's solution to the DEA's requirement, but the requirement is the same for all drug wholesalers.

3. How will this affect my pharmacy business?
There should be no significant impact to your business. The system monitors purchases of your controlled substances and compares them to your thresholds. We've taken care to set your threshold based on your controlled substance order history, and have put a program in place to give you plenty of notice if you are close to exceeding your threshold for a given product.

4. What changes will I see?
A new alert message will appear in your ordering system and on your invoice if you approach your threshold for a product. If you exceed your monthly purchase threshold, you will see the "V" omit code in your ordering system and on your invoice or delivery document to indicate the product has been omitted from your order because you exceeded your order limit.

5. McKesson states that you will be "monitoring" all of my controlled substances. How is this being done?
After conducting extensive analysis on controlled substances purchases, we have created a technology solution that has visibility to your controlled substances purchases and compares your purchases to your designated thresholds.

6. How are my thresholds determined?
Thresholds are established for each individual pharmacy. Your thresholds have been determined based on your 12-month purchase history.

7. McKesson states that I will receive an alert if I reach my threshold amount. How will I receive this notification?
Threshold alerts will appear for each product ordered on your invoice or delivery document. They will also appear in your electronic ordering system.

Attachment 7

8. What if I exceed my threshold?

You will always receive a threshold alert on your invoice or delivery document well in advance of exceeding your threshold, so you can monitor purchases or apply for a threshold change. If you still exceed your threshold, you will see the new code "V" with the message "Monthly Regulatory Maximum Purchases Exceeded" on your invoice, as well as in Order Acknowledgment or Invoice Acknowledgment (depending on your ordering system). That particular item will be omitted from your order and will not be shipped.

9. You said that McKesson is conducting real-time monitoring of controlled substance purchases according to DEA base code. How can I get more information on DEA base codes?

Please check the DEA Web site for all base codes and associated product categories: www.deadiversion.usdoj.gov/arcos/ndc/ndc_dic.htm.

10. What if I have a change in my business (for example, I acquire a new pharmacy or pursue another line of business)? Am I in danger of not being able to order enough product because of my previous order history?

We have created a Threshold Change Request process. If you do anticipate a change to your business, contact your McKesson sales representative as soon as possible so we can initiate the change request process.

11. How do I request a change in my threshold amounts?

Contact your McKesson sales representative.

12. Who do I contact if I have questions?

Contact your McKesson sales representative.

Attachment 7